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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,876	DOMB, ABRAHAM J.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-10 and 15-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *1-3, 6010 and 15-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of supplemental amendment and remarks filed 5/26/09. Receipt is also acknowledged for amendment to the specification.

The amendment to the specification filed 5/26/09 will be entered.

Claims 1, 6-8, 15 and 17 are amended. New claims 25-27 are added. Claims 4 are 5 canceled. Claims 1-3, 6-10 and 15-27 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 6-10 and 15-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

3. The specification as filed does not envision anhydride monomers or oligomers or polymers separated by random ester bonds.

4. The rejection may be overcome by deleting limitations that are not envisioned by the as filed specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Peterson et al. (US 6,303,138).

7. Peterson teaches bioactive composition comprising endothelin and a polymeric carrier (abstract and column 4, line 1). Preferred polymeric carrier is polyanhydride, polyester anhydride (column 4, line 35). The endothelin is a protein and thus meets the requirement of claim 2. The polyester anhydride by its name designation contains anhydride and ester functional bonds and meets the polyester anhydride requirement of the claims and each anhydride unit present as a repeating unit meets the monomeric anhydride unit of claim 1. Peterson does not state that the ester or anhydride bonds would be regular or random. But, bonds in molecules are either randomly or regularly spaced. However, because Peterson is silent as to the randomness or regularity of the arrangement of the ester bond, one having ordinary skill in that the esters separating the anhydride are either random or regular and absent factual showing the generic recitation of random ester bonds separating the anhydride monomers is not inventive over the Peterson art that is silent.

8. Claims 1, 3, 6, 7, 17, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Storey et al. (US 5,756,652).

9. Storey discloses biodegradable poly(ester-anhydrides) (abstract) as implants for controlled release of bioactive substances (column 1, lines 6-11; column 5, lines 15-22). When the polymer contains the bioactive substance, claims 1, 17 are met. The form suitable for injection is any form suitable and the Storey polymer is would be suitable for injection because it is for implantation so that claims 3 and 21 are met. The polyester anhydride compound according Storey comprises 2-20 polyester segments that are covalently bound through anhydride linkages and the polyester segment components comprise homopolymer or copolymer or terpolymer of biocompatible hydroxyl acids such as lactic acid, glycolic acid, ε-hydroxycaprioic acid (column 3, lines 22-44) with the hydroxyacid meeting the hydroxyl acids, such as glycolic acid, ε-hydroxycaproic acid and γ-hydroxy valeric acid, of claims 6, 7 and 25. The teaching that the 2 to 20 polyester segments are bound through anhydride linkages suggests that the anhydride are separated by random polyester bonds so that the anhydride linkages being separated by random polyester linkages in claims 1 and 17 are met. Storey contemplates the presence of multiple anhydride linkages (column 3, lines 64, 65) and variable number of anhydride units along the polymer backbone (column 9, lines 49-53).

Response to Arguments

10. Applicant's arguments filed 5/26/09 have been fully considered but they are not persuasive.

11. Applicant argues that it is the anhydride bonds in Storey that are random and not the ester bonds. The examiner disagrees with applicant that the ester bonds in Storey cannot be random.

First, applicant acknowledges that the polyester anhydride of comprises anhydride and ester bonds along the polymer chain. Second, applicant admits that the anhydride linkages in the polymer of Storey are random. Therefore, by applicant's own admission it would flow that if one segment of a polymer is random, then the other segments must be random also. Further, Storey discloses that the polyester anhydride has 2-20 polyester segments covalently bound through anhydride linkages (column 3, lines 24-28) without specifying that the anhydride linkage occurs at regular intervals of the polyester segments. If the anhydride linkages were present at regular polyester segment interval, then the anhydride linkages would be regular and the polyester segments would occur at regular intervals from the anhydride linkages. But, as admitted by applicant, the anhydride linkages are random and therefore, the polyester segments also randomly placed from the anhydrides and further also, 2-20 segments contemplates that the arrangement of the polyester segment is random.

12. Applicant also argues that the examiner alleges inherency without providing the basis and/or technical reasoning to reasonably support the allegation of inherency as required by the doctrine of inherency and that it is the anhydride that is random. The examiner disagrees. Once one member **A** is randomly placed in relation to other members **B** in a row, other members **B** must necessarily also be placed randomly with respect to members **A**. Furthermore, linkages or bonds are either random or regular and when the art is silent as to what the other is, then random or regular is reasonably inherent. This is the technical reasoning and the basis for the inherency assertion of the examiner which is now supported by applicant's admission that the anhydride is random. Furthermore, it is implicit that the arrangement of the polyester and the anhydride linkages be random because Storey discloses that 2-20 polyester segments are bound

through anhydride linkages Storey also discloses that there are multiple anhydride linkages, which is also admitted by the applicant. Therefore, basis is sound under the doctrine of inherency and further that random polyester and anhydride linkages are implicitly disclosed in Storey.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 3, 6-8, 15-19, 21, 22 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storey et al. (US 5,756,652) in view of Franson et al. (US 5,859,271) or Negishi et al. (US 5,480,787).

15. Storey has been described above to anticipate claims 1, 3, 6, 17, 21 and 25. Storey teaches that the polyester-anhydride is used as bioresorbable implant, that the polyester-anhydride can be used alone or in combination with biologically active ingredient to effect prolonged release of the biologically active agent. Storey goes on to say that the use and construction of devices such as polymeric implant devices for sustained or prolonged delivery of biologically active agents are known in the art and that the polyester-anhydride can be substituted for prior art polymer in the preparation of "such devices" (see column 5, lines 15-22).

16. The polyester segments in Storey can be formed from dihydric alcohol and biocompatible dicarboxylic acids, and representative carboxylic acids for forming prepolymer for the polyester-anhydrides include Kreb's cycle intermediates such as citric acid, α-ketoglutaric, succinic,

maleic, fumaric and cis-aconitic. However, sebacic acid, fumaric acid, maleic acid, oxalic acid and succinic acid are known to also esterify alcohols such as ricinoleic acid according to Franson at column 15, lines 11, 21. Also, Negishi discloses that esters are derived form carboxylic acid and alcohol; few of the carboxylic acids are linoleic acid, ricinoleic acid, succinic acid, fumaric acid and sebacic acid (column 2, lines 29, 40-48).

17. Therefore, taking the teachings of Storey, one having ordinary skill in the art at the time the invention was made would reasonably expect that prepolymers derived from esterification of ricinoleic acid with sebacic acid, fumaric acid, maleic acid, oxalic acid or succinic would be suitable for the preparation of the polyester-anhydride of Storey.

18. Those prepolymers derived from ricinoleic acid with sebacic acid, fumaric acid, maleic acid, oxalic acid or succinic contains sebacic and ricinoleic acid moieties so that claims 8, 15, 16, 18, 19, 22, 26 and 27 are met. Claims 8 and 22 are product by process claims. For claim 19, there is no demonstration in applicants specification tat the monomers derived from sebacic acid and ricinoleic acid using ratio of ricinoleic to sebacic in the range claimed provides unusual results.

19. Claims 1-3, 9, 10, 17, 20, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storey et al. (US 5,756,652) in view Brem et al. (US 5,846,565).

20. Storey has been described above to anticipate claims 1 and 17. Storey teaches that the polyester anhydride is used as bioresorbable implant, that the polyester-anhydride can be used alone or in combination with biologically active ingredient to effect prolonged release of the biologically active agent. Storey goes on to say that the use and construction of devices such as polymeric implant devices for sustained or prolonged delivery of biologically active agents are

known in the art and that the polyester-anhydride can be substituted for prior art polymer in the preparation of "such devices" (see column 5, lines 15-22). Storey does not disclose any specific biologically active agent. However, polymeric implants such as polyanhydride and polyester polymer implants have been known to deliver active agents such as chemotherapeutic agents to the target areas (title; abstract; column 5, lines 23-27, 42-45; column 6, line 42 to column 9, line 56 of Brem); Brem contemplates encapsulating the drugs (column 5, lines 29-32). Brem also contemplates polymeric carrier as microparticles, microsphere and microcapsules for encapsulating the drug (column 11, lines 46-50) with the microcapsule, microparticles and microsphere meeting the requirements of claims 9 and 23.

21. Thus, taking the teachings of Storey where the polyester-anhydride is used in combination with biologically active agent to provide release of the active agent upon implantation, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that the polyester-anhydride of Storey would release drugs upon implantation; drugs such as chemotherapeutic agents meeting the limitation of small drugs in claims 2 and 20.

22. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618